JS 44 (Rev. 12/07)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS
United States of America, ex rel. Amy Bergman, et. al.

(b) County of Residence of First Listed Plaintiff Palm Beach, FL
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number) Steven J. Engelmyer; Paul G. Gagne, 1650 Market St., 46th Fl., Phila., PA 19103; 215-568-2000

DEFENDANTS
Abbott Laboratories

County of Residence of First Listed Defendant Lake County, IL
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- XX 1 U.S. Government Plaintiff
- ☐ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	XX 2	XX 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury

PERSONAL INJURY
- ☐ 362 Personal Injury - Med. Malpractice
- ☐ 365 Personal Injury - Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 444 Welfare
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 440 Other Civil Rights

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence

Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition

FORFEITURE/PENALTY
- ☐ 610 Agriculture
- ☐ 620 Other Food & Drug
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 630 Liquor Laws
- ☐ 640 R.R. & Truck
- ☐ 650 Airline Regs.
- ☐ 660 Occupational Safety/Health
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 730 Labor/Mgmt.Reporting & Disclosure Act
- ☐ 740 Railway Labor Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 463 Habeas Corpus - Alien Detainee
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 810 Selective Service
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 875 Customer Challenge 12 USC 3410
- XX 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 892 Economic Stabilization Act
- ☐ 893 Environmental Matters
- ☐ 894 Energy Allocation Act
- ☐ 895 Freedom of Information Act
- ☐ 900Appeal of Fee Determination Under Equal Access to Justice
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN (Place an "X" in One Box Only)
XX 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION
Cite the U.S. Civil Statute under which you are filing **(Do not cite jurisdictional statutes unless diversity)**: 31 U.S.C. Section 3129 et. seq.
Brief description of cause: False Claims Act; Off Label Drug Marketing

VII. REQUESTED IN COMPLAINT: ☐ CHECK IF THIS IS A **CLASS ACTION** UNDER F.R.C.P. 23 **DEMAND $** In excess of $150,000.00 CHECK YES only if demanded in complaint: **JURY DEMAND:** ☐ Yes ☐ No

VIII. RELATED CASE(S) IF ANY N/A (See instructions): JUDGE _____ DOCKET NUMBER _____

DATE 9/18/09 SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I. (a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.C.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.

United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.

United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.

Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.

Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; federal question actions take precedence over diversity cases.)

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerks in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. Origin. Place an "X" in one of the seven boxes.

Original Proceedings. (1) Cases which originate in the United States district courts.

Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.

Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.

Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.

Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.

Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

Appeal to District Judge from Magistrate Judgment. (7) Check this box for an appeal from a magistrate judge's decision.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553
Brief Description: Unauthorized reception of cable service

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.

Demand. In this space enter the dollar amount (in thousands of dollars) being demanded or indicate other demand such as a preliminary injunction.

Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS 44 is used to reference related pending cases if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA — DESIGNATION FORM to be used by counsel to indicate the category of the case for the purpose of assignment to appropriate calendar.

Address of Plaintiff: 10858 King Bay Drive, Boca Raton, FL 33498

Address of Defendant: 100 Abbott Park Road, Abbott Park, IL 60064

Place of Accident, Incident or Transaction: Throughout the United States, including this District
(Use Reverse Side For Additional Space)

Does this civil action involve a nongovernmental corporate party with any parent corporation and any publicly held corporation owning 10% or more of its stock?

(Attach two copies of the Disclosure Statement Form in accordance with Fed.R.Civ.P. 7.1(a)) Yes☐ No☒

Does this case involve multidistrict litigation possibilities? Yes☐ No☒

RELATED CASE, IF ANY:

Case Number: _____ Judge _____ Date Terminated: _____

Civil cases are deemed related when yes is answered to any of the following questions:

1. Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court? Yes☐ No☒
2. Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court? Yes☐ No☒
3. Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action in this court? Yes☐ No☒
4. Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights case filed by the same individual? Yes☐ No☒

CIVIL: (Place ✔ in ONE CATEGORY ONLY)

A. *Federal Question Cases:*

1. ☐ Indemnity Contract, Marine Contract, and All Other Contracts
2. ☐ FELA
3. ☐ Jones Act-Personal Injury
4. ☐ Antitrust
5. ☐ Patent
6. ☐ Labor-Management Relations
7. ☐ Civil Rights
8. ☐ Habeas Corpus
9. ☐ Securities Act(s) Cases
10. ☐ Social Security Review Cases
11. ☒ All other Federal Question Cases
(Please specify) False Claims Act

B. *Diversity Jurisdiction Cases:*

1. ☐ Insurance Contract and Other Contracts
2. ☐ Airplane Personal Injury
3. ☐ Assault, Defamation
4. ☐ Marine Personal Injury
5. ☐ Motor Vehicle Personal Injury
6. ☐ Other Personal Injury (Please specify)
7. ☐ Products Liability
8. ☐ Products Liability — Asbestos
9. ☐ All other Diversity Cases
(Please specify)

ARBITRATION CERTIFICATION

(Check appropriate Category)

I, Paul G. Gagne, counsel of record do hereby certify:

☒ Pursuant to Local Civil Rule 53.2, Section 3(c)(2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of $150,000.00 exclusive of interest and costs;

☐ Relief other than monetary damages is sought.

DATE: 9/18/09 Attorney-at-Law 42009 Attorney I.D.#

NOTE: A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38.

I certify that, to my knowledge, the within case is not related to any case now pending or within one year previously terminated action in this court except as noted above.

DATE: 9/18/09 Attorney-at-Law 42009 Attorney I.D.#

CIV. 609 (6/08)

UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA — DESIGNATION FORM to be used by counsel to indicate the category of the case for the purpose of assignment to appropriate calendar.

Address of Plaintiff: 10858 King Bay Drive, Boca Raton, FL 33498

Address of Defendant: 100 Abbott Park Road, Abbott Park, IL 60064

Place of Accident, Incident or Transaction: Throughout the United States, including this District
(Use Reverse Side For Additional Space)

Does this civil action involve a nongovernmental corporate party with any parent corporation and any publicly held corporation owning 10% or more of its stock?

(Attach two copies of the Disclosure Statement Form in accordance with Fed.R.Civ.P. 7.1(a)) Yes☐ No☒

Does this case involve multidistrict litigation possibilities? Yes☐ No☒

RELATED CASE, IF ANY:

Case Number: _____ Judge _____ Date Terminated: _____

Civil cases are deemed related when yes is answered to any of the following questions:

1. Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court? Yes☐ No☒
2. Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court? Yes☐ No☒
3. Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action in this court? Yes☐ No☒
4. Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights case filed by the same individual? Yes☐ No☒

CIVIL: (Place ✔ in ONE CATEGORY ONLY)

A. *Federal Question Cases:*

1. ☐ Indemnity Contract, Marine Contract, and All Other Contracts
2. ☐ FELA
3. ☐ Jones Act-Personal Injury
4. ☐ Antitrust
5. ☐ Patent
6. ☐ Labor-Management Relations
7. ☐ Civil Rights
8. ☐ Habeas Corpus
9. ☐ Securities Act(s) Cases
10. ☐ Social Security Review Cases
11. ☒ All other Federal Question Cases
(Please specify) False Claims Act

B. *Diversity Jurisdiction Cases:*

1. ☐ Insurance Contract and Other Contracts
2. ☐ Airplane Personal Injury
3. ☐ Assault, Defamation
4. ☐ Marine Personal Injury
5. ☐ Motor Vehicle Personal Injury
6. ☐ Other Personal Injury (Please specify)
7. ☐ Products Liability
8. ☐ Products Liability — Asbestos
9. ☐ All other Diversity Cases
(Please specify)

ARBITRATION CERTIFICATION

(Check appropriate Category)

I, Paul G. Gagne, counsel of record do hereby certify:

☒ Pursuant to Local Civil Rule 53.2, Section 3(c)(2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of $150,000.00 exclusive of interest and costs;

☐ Relief other than monetary damages is sought.

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NOTE: A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38.

I certify that, to my knowledge, the within case is not related to any case now pending or within one year previously terminated action in this court except as noted above.

DATE: 9/18/09 _____ Attorney-at-Law 42009 Attorney I.D.#

CIV. 609 (6/08)

APPENDIX I

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

CASE MANAGEMENT TRACK DESIGNATION FORM

United States of America, ex rel. Amy Bergman, et al.	:	CIVIL ACTION
v.	:	
Abbott Laboratories	:	
	:	NO.

In accordance with the Civil Justice Expense and Delay Reduction Plan of this court, counsel for plaintiff shall complete a case Management Track Designation Form in all civil cases at the time of filing the complaint and serve a copy on all defendants. (See § 1:03 of the plan set forth on the reverse side of this form.) In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a case management track designation form specifying the track to which that defendant believes the case should be assigned.

SELECT ONE OF THE FOLLOWING CASE MANAGEMENT TRACKS:

(a) Habeas Corpus – Cases brought under 28 U.S.C. §2241 through §2255. ( )

(b) Social Security – Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits ( )

(c) Arbitration – Cases required to be designated for arbitration under Local Civil Rule 53.2. ( )

(d) Asbestos – Cases involving claims for personal injury or property damage from exposure to asbestos. ( )

(e) Special Management – Cases that do not fall into tracks (a) through (d) that are commonly referred to as complex and that need special or intense management by the court. (See reverse side of this form for a detailed explanation of special management cases.) (X)

(f) Standard Management – Cases that do not fall into any one of the other tracks. ( )

9/18/09	Paul G. Gagne	Plaintiff/Relator Amy Bergman
Date	**Attorney-at-law**	**Attorney for**
215-568-2000	215-568-0140	pgagne@kleinbard.com
Telephone	**FAX Number**	**E-Mail Address**

(Civ. 660) 10/02

Civil Justice Expense and Delay Reduction Plan
Section 1:03 - Assignment to a Management Track

(a) The clerk of court will assign cases to tracks (a) through (d) based on the initial pleading.

(b) In all cases not appropriate for assignment by the clerk of court to tracks (a) through (d), the plaintiff shall submit to the clerk of court and serve with the complaint on all defendants a case management track designation form specifying that the plaintiff believes the case requires Standard Management or Special Management. In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a case management track designation form specifying the track to which that defendant believes the case should be assigned.

(c) The court may, on its own initiative or upon the request of any party, change the track assignment of any case at any time.

(d) Nothing in this Plan is intended to abrogate or limit a judicial officer's authority in any case pending before that judicial officer, to direct pretrial and trial proceedings that are more stringent than those of the Plan and that are designed to accomplish cost and delay reduction.

(e) Nothing in this Plan is intended to supersede Local Civil Rules 40.1 and 72.1, or the procedure for random assignment of Habeas Corpus and Social Security cases referred to magistrate judges of the court.

SPECIAL MANAGEMENT CASE ASSIGNMENTS
(See §1.02 (e) Management Track Definitions of the
Civil Justice Expense and Delay Reduction Plan)

Special Management cases will usually include that class of cases commonly referred to as "complex litigation" as that term has been used in the Manuals for Complex Litigation. The first manual was prepared in 1969 and the Manual for Complex Litigation Second, MCL 2d was prepared in 1985. This term is intended to include cases that present unusual problems and require extraordinary treatment. See §0.1 of the first manual. Cases may require special or intense management by the court due to one or more of the following factors: (1) large number of parties; (2) large number of claims or defenses; (3) complex factual issues; (4) large volume of evidence; (5) problems locating or preserving evidence; (6) extensive discovery; (7) exceptionally long time needed to prepare for disposition; (8) decision needed within an exceptionally short time; and (9) need to decide preliminary issues before final disposition. It may include two or more related cases. Complex litigation typically includes such cases as antitrust cases; cases involving a large number of parties or an unincorporated association of large membership; cases involving requests for injunctive relief affecting the operation of large business entities; patent cases; copyright and trademark cases; common disaster cases such as those arising from aircraft crashes or marine disasters; actions brought by individual stockholders; stockholder's derivative and stockholder's representative actions; class actions or potential class actions; and other civil (and criminal) cases involving unusual multiplicity or complexity of factual issues. See §0.22 of the first Manual for Complex Litigation and Manual for Complex Litigation Second, Chapter 33.

IN THE UNITED STATES DISTRICT COURT FOR
THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA *ex rel.* AMY BERGMAN; the DISTRICT of COLUMBIA *ex rel.* AMY BERGMAN, CALIFORNIA *ex rel.* AMY BERGMAN, DELAWARE *ex rel.* AMBY BERGMAN, FLORIDA *ex rel.* AMY BERGMAN, GEORGIA *ex rel.* AMY BERGMAN, HAWAII *ex rel.* AMY BERGMAN, ILLINOIS *ex rel.* AMY BERGMAN, INDIANA *ex rel.* AMY BERGMAN, LOUISIANA *ex rel.* AMY BERGMAN, MASSACHUSETTS *ex rel.* AMY BERGMAN, MICHIGAN *ex rel.* AMY BERGMAN, MONTANA *ex rel.* AMY BERGMAN, NEVADA *ex rel.* AMY BERGMAN, NEW HAMPSHIRE *ex rel.* AMY BERGMAN, NEW JERSEY *ex rel.* AMY BERGMAN, NEW MEXICO *ex rel.* AMY BERGMAN, NEW YORK *ex rel.* AMY BERGMAN, OKLAHOMA *ex rel.* AMY BERGMAN, RHODE ISLAND *ex rel.* AMY BERGMAN, TENNESSEE *ex rel.* AMY BERGMAN, TEXAS *ex rel.* AMY BERGMAN, VIRGINIA *ex rel.* AMY BERGMAN, WISCONSIN *ex rel.* AMY BERGMAN, and AMY BERGMAN, individually, Plaintiffs v. ABBOTT LABORATORIES, Defendant	:	CIVIL ACTION NO. JURY TRIAL DEMANDED

COMPLAINT

Plaintiff-Relator Amy Bergman brings this civil action for the United States of America and the states of District of Columbia, California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Michigan, Montana, Nevada, New Hampshire, New Jersey,

New Mexico, New York, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Wisconsin and for herself and against Abbott Laboratories ("Abbott").

This is an action to recover damages and civil penalties on behalf of the United States and the Plaintiff-Relator arising from false and/or fraudulent statements and claims made, used and caused to be made used or presented by Defendant Abbott and/or its agents and employees in violation of the Federal False Claims Act, 31 U.S.C. §§ 3729 et seq. and the false claims acts of various states, specifically, In favor of Plaintiff-Relator Bergman for the maximum amount allowed as Relator's share pursuant to the Plaintiff State FCAs as follows: the Illinois Whistleblower Reward and Protection Act, 740 ILCS 175, *et seq.,* the California False Claims Act, Cal. Civ. Gov. Code §12651(a), the Delaware False Claims and Reporting Act, Del. Stat. Tit. VI. *§1201, et seq.,* the District of Columbia False Claims Act, D.C. Stat. §2-308.03 *et seq.,* the Florida False Claims Act, Ft. Stat. §§68.081-68.09, *et seq.,* the Hawaii False Claims Act, Haw. Rev. Stat. §661-21 *et seq.,* the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. §46-437, *et seq.,* Massachusetts False Claims Act, Mass. Gen. Laws c.12 §5(A), *et seq.,* the Michigan Medicaid False Claims Act, M.C.L.A. 400.601 *et seq.;* Michigan Public Acts, 1977 PA 72, as amended by 1984 PA 333, as amended by 2005 PA 337, as amended by 2008 PA 421; the Montana False Claims Act, 2005 Mont. Code, CH. 465, HB 146, *et seq.,* the Nevada False Claims Act, Nevada Rev. Stat. §357.010 *et seq.,* the New Hampshire False Claims Act, 167:61-b *et seq..,* the New Mexico False Claims Act, N.M. Stat ANN. §27-14-1 *et seq.;* New Mexico Fraud Against Taxpayers Act , N.M. Stat. § 44-9-1 *et seq.;* the New York False Claims Act, State Finance Law, §187 *et seq.;* the Tennessee Medicaid False Claims Act, Tenn. Stat. §§75-1-1 81 *et seq.;* the Tennessee False Claims Act Term. Code Ann. § 4-18-101 *et seq.;* the Texas Medicaid Fraud Prevention Act, Tx. Human Resources

Code, Ch. 36, §36.10I *et seq.*, Indiana False Claims and Whistleblower Act, IC 541-5.5 *et seq.*, Georgia State False Medicaid Claims Act, Ga. Code 49-4-168 *et seq.*, and the Virginia Fraud Against Taxpayers Act, Va. Stat. Ch. 842, Article 19.1, § 8.01-216.1 *et seq.;* New Jersey False Claims Act, N.J. STAT. § 2A:32C-1; Oklahoma Medicaid False Claims Act, 63 Okla. Stat. § 5053, *et seq.;* Wisconsin False Claims for Medical Assistance Act, WIS. STAT. § 20.931, *et seq.;* and the Rhode Island False Claims Act, R.I, Gen. Laws § 9-1.1-1. *et seq.*

In support hereof, Plaintiff-Relator avers as follows:

INTRODUCTION

In order to expand the sales of TriCor, Abbott engaged in a nationwide, coordinated deceptive program of false and misleading promotion and marketing of the pharmaceutical TriCor. Abbott's marketing scheme constitutes off-label marketing and misbranding. In order to effectuate its unlawful marketing program, Abbott promoted TriCor as a first-line treatment for diabetic patients even though it is not approved for such use. Abbott also promoted TriCor for use in combination with statins without the specific warnings set forth in the FDA-approved Product Insert. Abbott has engaged in a scheme to make representations concerning the efficacy of TriCor which are also contrary to the Product Insert, are false and misleading, and do not represent a fair balance of information. As a direct result of such off-label marketing and misbranding, physicians prescribed TriCor for off-label uses and have submitted claims for reimbursement to the federal government in connection with such prescriptions, giving rise to liability under the False Claims Act. The United States and the several states would not have paid such claims but for Abbott's illegal and fraudulent conduct.

PARTIES

1. Plaintiff-Relator Amy Bergman ("Bergman") resides and is domiciled at 10858 King Bay Drive, Boca Raton, Florida 33498, and is a citizen of the State of Florida.

2. Defendant Abbott Laboratories ("Abbott") is a corporation organized under the laws of the State of Illinois with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064, and is a citizen of Illinois. Abbott regularly transacts business in this judicial district.

JURISDICTION AND VENUE

3. This is a civil action arising under the laws of the United States to redress violations of 31 U.S.C. §§ 3729 et seq. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, 31 U.S.C. § 3732 and 28 U.S.C. § 1345.

4. Jurisdiction and venue are proper in this judicial district because this is a district in which an act proscribed by 31 U.S.C. § 3729 occurred, and under 31 U.S.C. § 3730(b)(1) because Abbott is qualified to do business in Pennsylvania and transacts business within this district.

5. This action is not based upon allegations or transactions which are the subject of a civil suit or an administrative civil money penalty proceeding in which the United States is already a party.

6. This action is not based upon public disclosure of allegations or transactions in a criminal, civil, or administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media.

7. To the extent there has been a public disclosure unknown to Bergman, Bergman is an original source under 31 U.S.C. § 3730(e)(4). She has direct and independent knowledge of the information on which the allegations of this complaint are based and has voluntarily provided the information to the Government before filing this action based on the information.

8. Bergman shall provide to the Attorney General and the United States Attorney for the Eastern District of Pennsylvania, a written disclosure of substantially all material evidence and information Bergman possesses.

BACKGROUND FACTS

9. Abbott is engaged in the business of manufacturing and selling pharmaceuticals. At all times relevant to this action, Abbott maintained a national sales force organized and supported under the direction of Abbott's national office in Abbott Park, Illinois.

10. Abbott's sales and marketing in the United States are organized by geographic areas under the direction of its national sales office. Each area is organized into regions, and each region is organized into districts and marketing territories. Abbott employs sales representatives with responsibilities for certain products within a territory. Sales materials and training are provided by or under the direction of the national office. Abbott's sales representatives receive incentive-based compensation that includes an annual salary plus a bonus based on sales within the relevant market.

11. Abbott began marketing TriCor (fenofibrate) in 1998.

12. From July 1, 1999, through January, 2008, Amy Bergman was employed by Abbott as a sales representative in its southeast area. From January, 2000 through January, 2008, Bergman was responsible for marketing TriCor in certain territories in Florida. Bergman received training and sales materials from Abbott and she attended quarterly training sessions run by representatives of Abbott's national sales office. Bergman was the lead TriCor sales representative in her region. Bergman is personally familiar with Abbott's marketing campaign for TriCor and the manner in which its marketing strategies for TriCor were implemented.

13. Bergman gained an in-depth knowledge of the off-label sales practices of Abbott.

14. The pharmaceutical industry is highly regulated by the Food and Drug Administration ("FDA").

15. Pursuant to the Food, Drug and Cosmetics Act, 21 U.S.C. §§ 301 et seq. (the "ACT"), the FDA strictly regulates the content of consumer and physician-based advertising, direct-to-physician product promotion, and drug labeling information used by pharmaceutical companies in promoting and selling FDA approved prescription drugs.

16. Under the Act, pharmaceutical drugs may not be marketed in the United States unless the sponsor of the drug demonstrates to the satisfaction of the FDA that the drug is effective and safe for each of its intended uses. 21 U.S.C. § 355 (a) and (d). Approval of the drug is the final stage of a multi-year process of study and testing.

17. Under 21 C.F.R. § 202.1(k)(2), any brochures, handouts, slide shows or other such promotional materials aimed at physicians are deemed to be "product labeling" which is regulated as such.

18. Under relevant FDA regulations, product labeling must be pre-approved by the FDA and conform to very exacting requirements concerning, among other things, drug interactions, warnings, indicated uses and claims concerning efficacy of a drug or its superiority over competing products.

19. All claims made in any labeling material must be truthful, not misleading and represent a fair balance of the information presented.

20. Any presentations, promotions, or marketing to physicians for products other than as approved for labeling purposes by the FDA is considered "off label" marketing and is thus prohibited by FDA regulation.

21. Any failure to fairly and accurately represent the required information about a prescription drug is considered misbranding and is a false and fraudulent statement as a matter of law. See 21 U.S.C. §§ 331(a) and (b), 352(a), (f) and (n); 21 C.F.R. § 201.57.

22. Pharmaceutical promotional and marketing materials and presentations lacking in fair balance or that are otherwise false or misleading violate the Food Drug and Cosmetics Act, 21 U.S.C. §§ 301 et seq., and regulations promulgated hereunder. Such violations exist where promotional and marketing materials and presentations for an FDA approved drug:

(a) Minimize, understate or misrepresent the risks, contra-indications and complications associated with that drug;

(b) Reference "off label" uses of the drug which were not FDA-approved indications, or expressly or implicitly promote unapproved uses and dosing regimens for which the drug is not indicated;

(c) Make comparative claims about the drug that have not been demonstrated by substantial evidence, such as comparisons with competing drugs and/or drug indications of patient usage, warnings and safety claims including side effects, physician preference, or

(d) Are otherwise false, misleading or lacking in fair balance in the presentation of information about the drug being marketed or any competing drug.

23. Whether a drug is FDA-approved for a particular use will largely determine whether a prescription for that use will be reimbursed under Medicaid and other federal health care programs.

24. The FDA does not approve a drug for treatment of sickness in general. Instead, a drug is approved for treatment of a specific condition, for which the drug has been tested in patients. The specific approved use is called the "indication" for which the drug may be prescribed. The FDA will specify particular dosages determined to be safe and effective for each indication.

25. The indication and dosages approved by the FDA are set forth in the drug's labeling, the content of which is also reviewed and approved by the FDA. 21 U.S.C. §§352, 355(d). An example of the drug's labeling is the printed insert in the drug's packaging. The FDA will only approve the new drug application if the labeling conforms to the uses and dosages that the FDA has approved. 21 U.S.C. §355(d).

26. Under the Food and Drug Administration Modernization Act of 1997 ("FDAMA"), if a manufacturer wishes to market or promote an approved drug for alternative use, *i.e.,* uses not listed on the approved label, the manufacturer must resubmit the drug for another series of clinical trials similar to those for the initial approval. 21 U.S.C. §360aaa(b) & (c). Until subsequent approval of the new use has been granted, the unapproved use is considered to be "off-label." "Off-label" refers to the use of an approved drug for any purpose, or in any manner, other than what is described in the drug's labeling. Off-label use includes treating a condition not indicated on the label, treating the indicated condition at a different dose or frequency than specified in the label, or treating a different patient population (e.g., treating a child when the drug is approved to treat adults).

27. Although the FDA is responsible for ensuring that a drug is safe and effective for the specific approved indication, the FDA does not regulate the practice of

medicine. Once a drug is approved for a particular use, the FDA does not prohibit doctors from prescribing the drug for uses that are different from those approved by the FDA.

28. Although physicians may prescribe drugs for off-label usage, the law prohibits drug manufacturers from marketing or promoting a drug for a use that the FDA has not approved. Specifically, under the Food and Drug laws, (1) a manufacturer may not introduce a drug into interstate commerce with an intent that it be used for an off-label purpose, and (2) a manufacturer illegally "misbrands" a drug if the drug's labeling (which includes all marketing and promotional materials relating to the drug) describes intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§331, 352.

29. An off-label use of a drug can cease to be off-label only if the manufacturer submits a supplemental application and demonstrates to the satisfaction of the FDA that the product is safe and effective for the proposed new use. 21 U.S.C. §360aaa(b)&(c).

30. In addition to prohibiting manufacturers from directly marketing and promoting a product's off-label uses, Congress and the FDA have also sought to prevent manufacturers from employing indirect methods to accomplish the same end. For example, Congress and the FDA have attempted to regulate two of the most prevalent indirect promotional strategies: (1) manufacturer dissemination of medical and scientific publications concerning the off-label uses of its products, and (2) manufacturer support for Continuing Medical Education (CME) programs that focus on off-label uses. With regard to the first practice – disseminating written information – the FDAMA only permits a manufacturer to disseminate information regarding off-label usage in response to an "unsolicited request from a health care practitioner." 21 U.S.C. §360aaa-6 (emphasis added). In any other circumstance, a manufacturer is permitted to disseminate information concerning the off-label uses of a drug only after the manufacturer

has submitted an application to the FDA seeking approval of the drug for the off-label use; has provided the materials to the FDA prior to dissemination; and the materials themselves must be in an unabridged form and must not be false or misleading. 21 U.S.C. §§360aaa(b)&(c); 360aaa-1.

31. With regard to manufacturer involvement in CME programs, the FDA's examination of these practices led to publication of an agency enforcement policy in 1997 entitled, "Guidance for Industry: Industry-Supported Scientific and Educational Activities," 62 Fed. Reg. 64,074, 64,093, 1997 WL 740420 (F.R.) (1997). This guidance document states that CME programs must be truly independent of the drug companies, and sets forth a number of factors that the FDA will consider in determining whether a program is "free from the supporting company's influence and bias." *Id.* These factors include, among others, an examination of the relationship between the program provider and supporting company, the company's control of content and selection of presenters, whether there is a meaningful disclosure of the company's funding and role in the program, whether multiple presentations of the same program are held, whether the audience is selected by the sales and marketing department of the company, and whether information about the supporting company's product is disseminated after the initial program other than in response to an unsolicited request. *Id.* The promotion of off-label drug uses at a CME program which fails this test of "independence" violates Congress' off-label marketing restrictions.

32. In sum, the off-label regulatory scheme protects patients and consumers by insuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific governmental body, the FDA.

33. The FDA has approved TriCor for the treatment of specific medical conditions accompanied by certain warnings and restrictions. The FDA also has approved a specific product insert for TriCor (the "Product Insert").

34. Abbott, seeking to bolster TriCor revenues, launched a campaign intended to increase Government-funded off-label purchases of TriCor by inducing physicians to prescribe TriCor through off-label promotion. The natural, intended and foreseeable effect of such unlawful conduct claims to be submitted to government-funded health plans that were ineligible for reimbursement pursuant to these programs' regulations.

35. Each such claim Abbott knowingly caused to be submitted to the government for reimbursement in derogation of the labeling and misbranding laws, and each false statement it made to cause claims to get claims for TriCor paid, constitutes a false claim for which Abbott is accountable under the Federal False Claims Act and state false claims acts.

The TriCor Product Insert

36. TriCor is described in the Product Insert as a "lipid regulating agent."

37. TriCor is indicated as adjunctive therapy to diet for treatment of adult patients with hypercholesterolemia, mixed dyslipedemia, or hypertriglyceridemia.

38. TriCor is not approved or indicated as a first-line drug for treatment of such patients, including the diabetic patient.

39. With regard to the efficacy of TriCor in producing positive cardiovascular outcomes, the Product Insert states: "The effect of TriCor on cardiovascular morbidity and mortality and non-cardiovascular mortality has not been established."

40. With regard to the use of TriCor in combination with statins, the Product Insert contains specific warnings. Under the heading "WARNINGS," the Product Insert states: "The combined use of TriCor and HMG-CoA reductase inhibitors [statins] should be avoided

unless the benefit of further alterations in lipid levels is likely to outweigh the increased risk of this drug combination."

41. The Product Insert further indicates that such combination uses of fibric acid derivatives [such as TriCor] and statins are associated with rhabdomyolysis, markedly elevated creatine kinase levels and myoglobinuria, leading in a high proportion of cases to acute renal failure.

First-Line Treatment for Patients With Diabetes

42. A key component of Abbott's unlawful marketing of TriCor has been that the drug should be utilized as a first-line drug for treatment of diabetic patients.

43. Abbott marketed TriCor as a first-line drug for treatment of diabetic patients even though Abbott possessed no test data demonstrating its efficacy or safety in this population.

44. Abbott's marketing of TriCor as a first-line drug for treatment of diabetic patients constitutes off-label promotion of TriCor.

45. Abbott's sales representatives were instructed to stress the benefits of fibrates such as TriCor over statins for the diabetic patient. Specifically, they were instructed to promote TriCor to physicians for treatment of diabetics by citing the VA-HIT subgroup analysis (studying the benefits of fibrates over statins for the diabetic patient and for a reduction in cardiovascular events) and by claiming it showed that fewer patients had to be treated with a fibrate like TriCor compared to a statin like Zocor before one sees a reduction in events.

46. The VA-HIT Trials was another study of the effects of Lopid (Gemfibrizol), not TriCor. The VA-HIT Trials reported reduced coronary mortality in diabetics and a reduced rate of certain cardiac events. Although TriCor was not involved in the study,

Abbott instructed its sales representatives to use the VA-HIT Study to respond to doctors' concerns as to the lack of outcomes data for TriCor. Abbott's efficacy claims based on the VA-HIT Trials were not supported by the data and were contrary to the Product Insert.

47. Abbott instructed sales representatives to use the subgroup analysis to convince physicians that TriCor was the better drug of choice for the subset of diabetic patients which were the subject of the subgroup analysis.

48. The release of the Heart Protection Study (HPS) subgroup analysis had a dramatic effect on physicians' treatment of diabetic and other high risk patients, which resulted in a change in Abbott's marketing strategy. As a result of the HPS subgroup analysis, many physicians concluded that every high-risk patient (diabetic, CHD) should be placed on a statin as first-line treatment, regardless of the patient's lipid levels. This was a marketing obstacle for TriCor because physicians would not consider TriCor as a first-line treatment for patients with high lipid levels. Abbott marketing's response was to instruct its sales representatives to "Paint the Picture" of a diabetic or CHD patient in their presentations to physicians.

49. If the patient was already on statin therapy, the representatives were instructed to use the VA-HIT trial to convince the physician to prescribe TriCor in addition to a statin for the patient who needed further lipid reduction.

50. If the patient was not already being treated with a statin drug, Abbott's sales representatives were instructed to urge the doctors to prescribe TriCor as a first-line treatment for the diabetic patient.

51. To support the off-label marketing, Abbott's sales representatives were instructed to use the VA-HIT study (outcomes data for the fibrate Gemfibrozil) to encourage the physician to prescribe TriCor (a different fibrate) for this patient type, even though that study did

not involve TriCor and therefore did not support that claim. The sales representatives were also encouraged to utilize the Heart Protection Study subgroup analysis (which suggested that Gemfibrozil, as compared to Zocor, required fewer patients to reduce the likelihood of an adverse cardiovascular event) to show that fibrates as a class are better than statins for the diabetic patient.

52. In addition to utilizing the subgroup analysis results for Gemfibrozil, a fibrate, to promote a "class effect" for the entire fibrate class (including TriCor), the sales representatives were also told to make efficacy claims for TriCor as a superior fibrate by telling physicians that TriCor is safer and more potent than Gemfibrozil. Abbott encouraged the sales representatives to make presentations in which the representatives encouraged physicians to write for TriCor rather than Gemfibrozil because TriCor was more efficacious than Gemfibrozil in reducing triglycerides and increasing HDL, and because the physicians would see better outcomes in their diabetic patients. Abbott sales representatives were encouraged to utilize actual patients' lab results to illustrate the efficacy of TriCor in order to generate sales.

53. From approximately 2006 through Bergman's termination in 2008, Abbott's sales representatives were also instructed to use a non-branded sales aid because this detail piece included a summary of studies that sales representatives were encouraged to use at will to suit Abbott's marketing message. None of the studies in the compendium was based on any outcomes data for TriCor, and therefore the sales aid did not support the efficacy claims for TriCor which were made to physicians.

54. The "Paint the Picture" concept of a TriCor patient type (diabetic or CHD) was presented at all of Abbott's national and regional sales meetings, role playing exercises, and similar functions.

55. The DAIS Trial was another study provided to Abbott representatives throughout the country in 2003, sometime before the Field Trial was released. Abbott sales representatives attending Abbott's regional sales meetings were trained by national marketing and by Abbott's district managers to use the DAIS Trial study in their sales presentations to doctors. Although the DAIS study was not mentioned on the TriCor label, the sales representatives were instructed to summarize the article and stress the positive points of the study in presentations to physicians.

56. The DAIS Trial study was utilized by Abbott from approximately 2003 until at least Bergman's termination in 2008.

57. The DAIS Trial study was utilized to show "Outcomes for TriCor." The sales representatives were instructed to stress that the study was conducted by the World Health Organization, not Abbott Laboratories.

58. Initially, sales representatives in the field were instructed by Abbott to tell physicians that DAIS was the first study to show that treating a Type II diabetic with TriCor slows the progression of coronary artery diseases, and that DAIS showed a 40% reduction in the progression of atherosclerosis and a reduction in clinical events by 23%. After sales representatives initially presented this information to physicians in the field, Abbott's corporate sales management realized that the information was not recognized by physicians as valid outcomes data because the design of the study was based on angiographic data. Despite that, sales representatives continued to utilize the DAIS Trial in support of sales presentations but it was not emphasized to the same extent as before to convince physicians that DAIS showed there was positive outcomes data for the treatment of diabetic patients with coronary artery disease.

59. Abbott sales representatives were instructed to attend national/regional meetings quarterly to review and discuss Abbott's marketing strategy. The meeting were run by the sales trainers and members of the Abbott TRICOR Marketing team.

60. Representatives were trained on how to promote TriCor to physicians and were instructed to focus on the diabetic patient type. Representatives were told that the diabetes market is expanding at an increasing rate and that they should target diabetic patients.

61. The benefits of TriCor as a first-line drug for the treatment of patients with diabetes were stressed to physicians in sales calls by Abbott's sales representatives from 2002 to 2008.

62. Abbott's sales representatives were given specific, detailed instructions for overcoming physician objections to the use of TriCor as a first-line treatment for diabetics, including stated preferences for other pharmaceuticals and objections based on the lack of outcomes data and concerns with product safety. The sales representatives were instructed to open calls with physicians by referencing diabetic patients with mixed dyslipidemia, in order to promote new business by specifically targeting such patients.

Combination Therapy.

63. Another key component of Abbott's illegal marketing of TriCor was promotion of its use in combination therapy by means of deceptive minimizing of the significant risks of such use.

64. Statins were widely prescribed by physicians as the primary choice for treatment of coronary heart disease. Abbott's marketing strategy was to enhance TriCor sales by promoting doctors' use of TriCor in combination with statins. That strategy, however, ran contrary to the Product Insert. The Product Insert makes clear that there are significant risks

associated with combined use of TriCor and statins, and that the benefits of TriCor on outcomes (morbidity and mortality) have not been established. The Product Insert cautions that TriCor should be used in combination with statins only where the benefits outweigh the risks.

65. As early as 2002 and continuing to 2008, Abbott instructed its sales representatives to promote TriCor for use in combination with statins without the appropriate warnings required by the FDA on the approved Product Insert.

66. Abbott instructed its sales representatives to target physicians who wrote large numbers of prescriptions for statins.

67. Abbott sales representatives were taught to promote combination therapy in meetings with physicians without discussing the risks, or the critical importance of weighing the benefit against the increased risk of combination therapy, as required by the Product Insert.

68. Abbott provided training and scripts to its sales representatives which instructed the representatives on how to interest and encourage doctors to prescribe TriCor in combination with statins. Contrary to the Product Insert, the training and scripts did not mention the risk of such combination therapy.

69. Abbott also provided its sales force with written promotional materials which touted the benefits of combination therapy involving TriCor and statins, without the Product Insert and without its warnings.

70. Abbott set up continuing medical education programs for physicians' license renewal credits. Abbott used the programs to promote TriCor. Abbott provided a speaker who supported combination therapy without discussing the dangers and without providing copies of the Product Insert.

71. Abbott identified pharmacists in Palm Beach County, Florida, who would not process prescriptions for TriCor in combination with a statin at all or without physician verification. Abbott then paid a physician to make presentations to area pharmacists regarding the use of TriCor in combination therapy. The physician's presentation did not include the Product Insert or any data about possible dangers of combination therapy.

72. The Merck Safari Study analyzed the effects of Zocor, a statin, in combination with TriCor. The Safari Study was not included on the Product Insert and the Study concluded that the reduction of coronary heart disease events was not significant in this trial. Nonetheless, Abbott sales representatives were taught to leave the Safari Study with doctors, and to discuss the safety and efficacy of Zocor and TriCor in combination therapy. These claims were not supported by the data and were directly contrary to the warnings on the Product Insert that the combination of TriCor and statins "should be avoided unless the benefit of further alterations in lipid levels is likely to outweigh the risk of this drug combination." Such promotion constitutes off-label marketing and misbranding.

73. At the same time, TriCor sales representatives were not provided with copies of another study of combination therapy involving TriCor and a statin (Pravachol). That study was included on the Product Insert to show the dangers of combination therapy. The study was not distributed by Abbott to physicians.

74. Abbott actively concealed off-label discussions regarding combination therapy. Abbott sales representatives were required to make "call notes" after meetings with doctors. However, Abbott instructed its representatives not to include off-label discussions in their call notes. Whenever Abbott representatives had off-label discussions with doctors

concerning the safety and efficacy of combination therapy, they were instructed to write the code "BOR" in their call notes.

Efficacy Claims

75. Abbott also illegally marketed TriCor by means of misleading efficacy claims.

76. Although the Product Insert states that TriCor's effect "on coronary heart disease morbidity and mortality and non-cardiovascular mortality has not been established," Abbott nonetheless promoted TriCor both alone and in combination therapy as having such positive outcomes.

77. A comprehensive study of TriCor (the FIELD Study) referenced in the Product Insert concluded that TriCor does not produce a significant decrease in coronary heart disease mortality. (There was actually an increase in such mortality but it was not statistically significant). Abbott provided the FIELD Study to doctors and coached its representatives on how to downplay its lack of positive outcome data regarding coronary heart disease mortality.

78. Instead, Abbott used the positive outcome data of studies involving fibrates other than TriCor to claim a class effect, that is, that TriCor would have the same positive outcomes as other fibrates. In some cases, Abbott claimed TriCor would produce better outcomes. There was no substantial evidence to support such claims and they were contrary to the Product Insert.

79. For example, the Helsinki Trials was a study of Lopid, a fibrate, which showed that Lopid caused a significant reduction in coronary heart disease deaths and heart attacks in the primary component of the study. The Helsinki Study did not involve TriCor. Nonetheless, Abbott sales representatives were taught to use the study to claim that fibrates as a class (including TriCor) caused a significant reduction in cardiac mortality and morbidity.

Abbott's use of the Helsinki Study is directly contrary to the Product Insert which cites the study for potential risks of fibrate therapy.

80. Although TriCor was not involved in the VA-HIT study, Abbott instructed its sales representatives to use the VA-HIT Study to respond to doctors' concerns as to the lack of outcomes data for TriCor. Abbott's efficacy claims based on the VA-HIT Trials were not supported by the data and were contrary to the Product Insert.

81. Abbott instructed sales representatives to use the DAIS Study to suggest that use of TriCor resulted in positive outcome data on coronary mortality and morbidity, although the DAIS Study did not examine cardiac events, mortality or outcomes. The DAIS Study was not included in the Product Insert and Abbott's claims of efficacy were not supported by the data.

82. Abbott sales representatives were also trained to compare the Merck Heart Protection Study involving a statin, to the VA–HIT trial involving Gemfibrozil, a fibrate, to convince doctors that TriCor was a superior agent to treat diabetic patients. The premise of this comparison was to illustrate that the fibrate outcomes was a class effect by comparing numbers intended to treat before an event . This use of the Merck Heart Protection as well as the VA-HIT trial was off-label, false and misleading, and made unsubstantiated efficacy claims for TriCor.

Payments to Doctors

83. In addition to its illegal promotional scheme, Abbott effectuated its fraudulent marketing scheme for TriCor by means of illegal kickbacks to physicians.

84. Abbott's sales representatives were taught to target doctors who wrote a large number of prescriptions for statins or for cholesterol drugs. Abbott then encouraged sales

representatives to find ways to reward doctors to induce them to write more prescriptions for TriCor.

85. Sales representatives paid for a targeted doctor's lunch or dinner. Some were solicited by payments for theater programs or professional football games and concerts. These events were usually accompanied by a brief talk about TriCor.

86. TriCor sales representatives were encouraged to organize dinner programs for doctors. Financing for these dinner "roundtables" was provided by Abbott's central office.

87. The speaker, a targeted doctor, would receive $500 or more and dinner at an expensive restaurant, at the physician's request and upon approval by Abbott. To provide an audience, the speaker would invite staff members, friends and practitioners and doctors in specialties unrelated to coronary care or cholesterol/triglyceride management.

88. Abbott has from time to time paid high volume TriCor prescription writers to serve as preceptors for a sales representative. Doctors were recruited as preceptors for the purpose of increasing their TriCor prescriptions.

89. Abbott paid doctors an honorarium to attend "Advisory Board Meetings" in vacation cities. Federal statutory and regulatory law prohibits kickbacks for the promotion of off-label drug usage. A pharmaceutical manufacturer or other entity may not offer remuneration in any form to a beneficiary that the company knows or should know is likely to influence the beneficiary to prescribe items from a particular supplier. 42 U.S.C. § 1320a-7a(a)(5); 1320a-7b(b).Kickbacks have the effect of reducing a patient's healthcare choices as paid physicians steer the patient to off-label products based on the physician's own financial interests, rather than the patient's medical needs. Kickbacks also undermine the physician's own medical judgment as to which drug to prescribe.

False Claims

90. Abbott through its unlawful sales practices knowingly caused prescriptions to be written for TriCor and claims for reimbursement to be submitted to the Untied States Government that would not have been written or submitted but for Abbott's unlawful sales practices.

91. Sales of TriCor based on Abbott's marketing of TriCor as a first-line treatment for the diabetic patient, claims for TriCor's efficacy contrary to the Product Insert, and claims for the benefit of TriCor in combination with statins without proper warnings required by the Product Insert were not medically accepted indications and therefore were not eligible for reimbursement under Medicaid, Medicare or other federal health care programs.

92. As a direct result of Abbott's improper off-label and misleading marketing practices for TriCor, health insurance programs funded by the United States including but not limited to Medicaid and Medicare, paid false or fraudulent TriCor reimbursement claims for prescriptions written to those programs' beneficiaries for off-label use. The United States would not have paid such claims but for Abbott's illegal and fraudulent conduct.

93. Abbott did not directly submit claims for prescription drugs to federal health insurance programs; however, Abbott knew – in fact, it was Abbott's goal – that its illegal off-label and misleading marketing practices would cause the submission of thousands of claims to government-funded health programs for prescriptions that should not have been issued and were not eligible for program reimbursement.

94. Abbott marketed TriCor as a first-line treatment for diabetic patients to many physicians, including without limitation the following:

Altman, Lynda
Antellis, Eugene

Apostolopoulos, Neostolopoulis
Arena, Joseph
Baine, Stuart
Baker, Leah
Barish, Susan
Baum, Seth
Berenson, Bruce
Berenson, Scott
Bruzzo, Michele
Caridi, Steven
Cohen, Meyer
Cohen, Steven
Cohen, Roy
Colton, Robert
Crescetelli, John
Deitsch, Gregory
Demarchi, William
Depodesta, Craig
Devine, Charles
Devon, Jeffrey
Diamond, Paul
Ehrlich, Laurence
Felker, David
Figueira, Christina
Gherghina, Valentina
Gomer, Alan
Grenn, Gordon
Gross, Jeffrey
Gruss, William
Gutierrez, Maria
Hevert, David
Himmelstein, Stuart
Horowitz, Barry
Jacob, Marty
Johnson, Charles
Jurado, Maria
Kaufmann, John
Lampert, Mitchell
Laracuente, Ronald
Lavernia, Frank
Levin, Bruce
Levin, Richard
Levinson, David
Lopez, Enrique
Lopez-Ivern, Fernando
Lopez-Padillo, Fran

Macia, Jorge
Mellman, Michael
Milbauer, David
Monahan, Kevin
Moraes, Brian
Neuman, David
Nicursor Ieremia
Portnoy, Dana
Rathbun, Kathleen
Rebello, Brian
Remenson, Ella
Rogovin, Mark
Rooptaz, Sibia
Rosenberg, Marc
Ross, Steven
Rowland, William
Santa Maria, Roderick
Scanlon, Mary
Schwartz, Paul
Seidman, Barry
Slotnick, David
Speizman, David
Spirazza, Carl
Sperduto, Joseph
Stampalia, Anthony
Strobis, John
Trejo, Rodolfo
Tumminia, Louis
Ukani, Zaib
Weatherford, Gregory
Weisman, Neal
Widdows, Joanna
Willey, Michele
Wishnov, Bruce

95. Physicians, including but not limited to the following, prescribed TriCor for diabetic patients:

Arena, Joseph
Barish, Susan
Berenson, Bruce
Caridi, Steven
Cohen, Meyer
Cohen, Steven
Depodesta, Craig

Devine, Charles
Felker, David
Hevert, David
Horowitz, Barry
Ieremia , Nicursor
Johnson, Charles
Lavernia, Frank
Levin, Richard
Levinson, David
Lopez, Enrique
Lopez-Padillo. Franco
Macia, Jorge
Mellman, Michael
Neuman, David
Portnoy, Dana
Ross, Steven
Seidman, Barry
Speizman, David
Sperduto, Joseph
Spirazza, Carl
Tumminia, Louis
Wishnov, Bruce

96. The following physicians informed Abbott sales representatives that they had prescribed TriCor for diabetic patients as a result of Abbott's marketing of TriCor as a first-line treatment for diabetics:

Berenson, Bruce
Cohen, Steven
Hevert, David
Ieremia , Nicursor
Johnson, Charles
Lavernia, Frank
Portnoy, Dana
Seidman, Barry
Spirazza, Carl
Wishnov, Bruce

Government Funded Healthcare Programs Damaged By Paying False TriCor Claims

97. The federal government reimburses a portion of the cost of prescription drugs under several other health care programs, including but not limited to Medicaid, Medicare, and Medicare Part D.

A. Medicaid

98. Title XIX of the Social Security Act is a program which provides medical assistance for certain individuals and families with low incomes and resources. The program, known as Medicaid, became law in 1965 as a jointly funded cooperative venture between the federal and state governments to assist states in the provision of adequate medical care to eligible needy Americans. Among the groups of people served by Medicaid are eligible low-income parents and children.

99. The Medicaid Program (42 U.S.C. §1395, *et seq.*) is administered through the Centers for Medicare and Medicaid Services (CMS), which is a division of the Department of Health and Human Services (HHS) of the federal government. Numerous states statutorily limit Medicaid reimbursement for prescription drugs to those uses approved by the FDA or when the prescribing physician makes a medical necessity certification after the identified patient has failed to respond to treatment with medications indicated for the patient's illness. This prohibition directly implicates Abbott's off-label marketing scheme because claims for off-label prescriptions were induced to be submitted to the United States for reimbursement without the required certification of medical necessity.

B. Medicare and Medicare Part D

100. Medicare is a government financial health insurance program administered by the Social Security Administration of the United States. The health insurance provided to

beneficiaries of the Medicare insurance program is paid in whole or in part by the United States. Medicare was promulgated to provide payment for medical services, durable medical equipment and other related health items for individuals 65 and over. Medicare also makes payment for certain health services provided to additional classes of needy classes of individual healthcare patients pursuant to federal regulation.

101. On December 8, 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "MMA"). Title I of the MMA created new outpatient prescription drug coverage under Medicare ("Medicare Part D").

102. Medicare Part D went into effect on January 1, 2006. The Program is administered by the United States Department of Health and Human Services, Centers for Medicare and Medicaid ("CMS"). For "dual eligibles," defined as individuals who received prescription drug coverage under Medicaid in addition to Medicare coverage for other health care in 2005, enrollment in Medicare Part D was compulsory. Such beneficiaries were automatically switched to the Part D plans for 2006 and commenced receiving comprehensive prescription drug coverage under Medicare Part D.

103. Coverage of prescription drugs under Medicare Part D is subject to the same regulations as coverage under the Medicaid Program described above.

104. As a direct, proximate and intended result of the conduct of Abbott alleged herein in violation of the Federal False Claims Act and the analogous laws of the plaintiff states, the Medicare and Medicare Part D programs have been damaged.

COUNT I

Violation of False Claims Act, 31 U.S.C. § 3729(a)(1)

105. Paragraphs 1 through 104 are incorporated herein as though set forth fully.

106. The False Claims Act, 31 U.S.C. § 3729(a)(1), provides that any person who knowingly submits or causes to be presented to the United States for payment or approval a false or fraudulent claim is liable to the United States for a civil penalty of not less than $5,500 and not more than $11,000 (adjusted as set forth in 28 C.F.R. § 85.3) for each such claim, plus three times the amount of damages sustained by the United States because of the false claims.

107. The False Claims Act allows any person with knowledge of a false or fraudulent claim against the United States to bring an action in the United States District Court for herself and for the United States and to share in any recovery as authorized by 31 U.S.C. § 3730. There are no bars to recovery under 31 U.S.C. § 3730(e) and Bergman is an original source as defined in the statute. Bergman claims entitlement to a portion of any recovery obtained by the United States as Relator and original source in this action.

108. By virtue of the acts described above, Abbott knowingly caused physicians to prescribe TriCor as a first-line treatment for patients with diabetes.

109. By virtue of the acts described above, Abbott knowingly caused physicians to prescribe TriCor for combination therapy together with statins.

110. By virtue of the acts described above, Abbott knowingly caused physicians to prescribe TriCor by making false efficacy claims.By virtue of the acts described above, Abbott knowingly caused to be presented to officers or employees of the Untied States government false or fraudulent claims for payment.

111. The United States, unaware of the falsity of the claims and statements made or caused to be made by Abbott, and in reliance on their accuracy, paid and continues to pay claims that would not have been paid but for Abbott's illegal marketing practices.

112. The amounts of the false or fraudulent claims were material. By reason of Abbott's acts, the United States has been damaged in a substantial amount. Federal health insurance programs have paid substantial amounts for prescriptions that were induced by Abbott's unlawful marketing practices.

WHEREFORE, Plaintiff-Relator Amy Bergman demands that this Court enter judgment against defendant Abbott Laboratories in an amount in excess of $150,000 exclusive of interest and costs, equal to three times the amount of damages sustained by the United States because of Abbott's actions, plus a civil penalty of not less than $5,500 and not more than $11,000 for each violation of 31 U.S.C. § 3729, and awarding to Amy Bergman the maximum amount allowed pursuant to § 3730(d) of the False Claims Act plus all her costs, expenses, and attorneys' fees to the extent permitted by law, and that the United States and Amy Bergman be awarded such other and further relief as this Court deems just and proper.

COUNT II

Violation of False Claims Act, 31 U.S.C. § 3729(a)(2)

113. Paragraphs 1 through 112 are incorporated herein as though set forth fully.

114. The False Claims Act, 31 U.S.C. § 3729(a)(2), provides that any person who knowingly makes, uses or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the government is liable to the United States for a civil penalty of not less than $5,500 and not more than $11,000 (adjusted as set forth in 28 C.F.R. § 85.3) for each such claim, plus three times the amount damages sustained by the United States because of the false claims. By the foregoing acts and omissions, including the payment of kickbacks, Defendant Abbott took actions in furtherance of its scheme to improperly promote TriCor, including but not limited to the payment of substantial sums of monies to physicians in

exchange for casting favorable light upon TriCor and for choosing TriCor for off-label use, thereby exponentially increasing the number of TriCor prescriptions submitted to the United States for payment.

115. The False Claims Act allows any person with knowledge of a false or fraudulent claim against the United States to bring an action in the United States District Court for herself and for the United States and to share in any recovery as authorized by 31 U.S.C. § 3730. There are no bars to recovery under 31 U.S.C. § 3730(e) and Bergman is an original source as defined in the statute. Bergman claims entitlement to a portion of any recovery obtained by the United States as Relator and original source in this action.

116. By virtue of the acts described above, Abbott knowingly caused physicians to prescribe TriCor as a first-line treatment for diabetic patients.

117. By virtue of the acts described above, Abbott knowingly caused physicians to prescribe TriCor for combination therapy together with statins.

118. By virtue of the acts described above, Abbott knowingly caused physicians to prescribe TriCor by making false efficacy claims.By virtue of the acts described above, Abbott knowingly caused false records or statements to be made to get false or fraudulent claims paid or approved by the Government.

119. The United States, unaware of the falsity of the claims and statements made or caused to be made by Abbott, and in reliance on their accuracy, paid and continues to pay claims that would not have been paid but for Abbott's illegal marketing practices.

120. The amounts of the false or fraudulent claims were material. By reason of Abbott's acts, the United States has been damaged in a substantial amount. Federal health

insurance programs have paid substantial amounts for prescriptions that were induced by Abbott's unlawful marketing practices.

WHEREFORE, Plaintiff-Relator Amy Bergman demands that this Court enter judgment against defendant Abbott Laboratories in an amount in excess of $150,000 exclusive of interest and costs, equal to three times the amount of damages sustained by the United States because of Abbott's actions, plus a civil penalty of not less than $5,500 and not more than $11,000 for each violation of 31 U.S.C. § 3729, and awarding to Amy Bergman the maximum amount allowed pursuant to § 3730(d) of the False Claims Act plus all her costs, expenses, and attorneys' fees to the extent permitted by law, and that the United States and Amy Bergman be awarded such other and further relief as this Court deems just and proper.

COUNT III
Violations of the Illinois Whistleblower Reward and Protection Act
740 ILCS 175/1 *et seq.*

121. Paragraphs 1 through 120 are incorporated herein as though set forth fully.

122. This Count is brought by Plaintiff-Relator Bergman in the name of the State of Illinois under the *qui tam* provisions of 740 ILCS 175/4 for Defendant's violation of 740 ILCS 175/3.

123. Defendant Abbott at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of Illinois, including TriCor.

124. The Illinois Whistleblower Reward and Protection Act, 740 III. Comp. Stat. §175/3 (a)(1)-(3), specifically provide that any person who:

(1) Knowingly presents, or causes to be presented, to an officer or employee of the State or member of the Guard a false or fraudulent claim for payment or approval;...

(2) Knowingly makes, uses or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the

State; ...

(3) Conspires to defraud the State by getting a false or fraudulent claim allowed or paid;...

(a) is liable to State for civil penalty of not less than $5,500 and not more than $11,000, plus 3 times the amount of damages which the State sustains because of the act of that person.

125. By virtue of the above-described acts, among others, Defendant Abbott knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Illinois, for TriCor.

126. Specifically, Defendant has:

- caused hundreds of thousands of false claims to be presented to the State of Illinois;
- knowingly made, used or caused to be made or used false records to get false claims paid;
- conspired to defraud the state, by getting false and fraudulent claims allowed or paid; and,
- tailed to disclose the existence of the false claims it has caused to be presented.

127. The amounts of the false or fraudulent claims to the State of Illinois were material.

128. Plaintiff State of Illinois, being unaware of the falsity of the claims caused to be submitted by the Defendant, and in reliance on the accuracy thereof paid and continues to pay for improperly prescribed TriCor.

COUNT FIVE
Violations of the California False Claims Act
Cal. Government Code §12650 *et seq.*

129. Paragraphs 1 through 128 are incorporated herein as though set forth fully.

130. This Count is brought by Plaintiff-Relator Bergman in the name of the State of California under the *qui tam* provisions of the California False Claims Act, California Government Code §12651(a), pursuant to which treble damages and civil penalties are sought.

131. Defendant Abbott at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals, including TriCor, in the State of California.

132. Cal. Govt. Code §12651(a) provides liability for the costs of a civil action, a civil penalty of up to $10,000 and treble damages for all damages sustained by the state for any person who-

(1) knowingly presents, or causes to be presented, to an officer or employee of the state or of any political subdivision thereof, a false claim for payment or approval;

(2) knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the state or any political subdivision;

(3) conspires to defraud the state or any political subdivision by getting a false claim allowed or paid by the state or by any political subdivision;

(4) is a beneficiary of an inadvertent submission of a false claim, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the state or the political subdivision within a reasonable time after discovery of the false claim.

133. By virtue of the above-described acts, among others, Defendant Abbott knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of California, for TriCor.

134. Specifically, Defendant has:

- caused hundreds of thousands of false claims to be presented to the State of California;
- knowingly made, used or caused to be made or used false records to get false claims paid;
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

135. The amounts of the false or fraudulent claims to the State of California were material.

136. Plaintiff State of California, being unaware of the falsity of the claims caused to be submitted by Defendant Abbott and in reliance, on the accuracy thereof paid and continues to pay for improperly prescribed TriCor.

COUNT SIX
Violations of the Delaware False Claims Act
Del. Stat. Tit. VI. §1201

137. Paragraphs 1 through 136 are incorporated herein as though set forth fully.

138. This Count is brought by Plaintiff-Relator Bergman in the name of the State of Delaware under the *qui tam* provisions of the Delaware False Claims and Reporting Act, Delaware Statute Title VI, Section 1201.

139. Defendant Abbott at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of Delaware, including TriCor.

140. The Delaware False Claims and Reporting Act, 6 Del Code Aim. §1201(a)(1) provides for liability for any person who:

> knowingly presents or causes to be presented, directly or indirectly, to an officer or employee of the Government a false or fraudulent claim for payment or approval; ... shall be liable to the Government for a civil. penalty of not less than $5,500 and not more than $11,000 for each act constituting a violation of this section, plus 3 times the amount of the actual damages which the Government sustains because of the act of that person.

141. The Delaware False Claims and Reporting Act, 6 Del. C. 1201(a)(2) provides for liability for any person who;

> knowingly makes, uses or causes to be made or used, directly or indirectly, a false record or statement to get a false or fraudulent claim paid or approved; ...shall be liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each act constituting a violation of this section, plus 3 times the amount of the actual damages which the Government sustains because of the act of that person.

142. The Delaware False Claims and Reporting Act, 6 Del. C. §1201(a)(3), provides for liability for any person who;

> Conspires to defraud the Government by getting a false or fraudulent claim allowed or paid; ... shall be liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each act constituting a violation of this section, plus 3 times the amount of the actual damages which the Government sustains because of the act of that person.

143. By virtue of the above-described acts, among others, Defendant Abbott knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Delaware, for TriCor.

144. Specifically, Defendant has:

- caused hundreds of thousands of false claims to be presented to the State of Delaware;
- knowingly made, used or caused to be made or used false records to get false claims paid;

- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,

- failed to disclose the existence of the false claims it has caused to be presented.

145. The amounts of the false or fraudulent claims to the State of Delaware were material.

146. Plaintiff State of Delaware, being unaware of the falsity of the claims caused to be submitted by the Defendant, and in reliance on the accuracy thereof paid and continues to pay for improperly prescribed TriCor.

COUNT SEVEN
Violations of the District of Columbia Procurement Reform Amendment Act,
D.C. Stat. § 2-308.14(a)(1)

147. Paragraphs 1 through 146 are incorporated herein as though set forth fully.

148. This Count is brought by Plaintiff-Relator Bergman in the name of the District of Columbia under the *qui tam* provisions of D.C. Stat. §2-308.03 *et seq*.

149. Defendant Abbott at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the District of Columbia, including TriCor.

150. The District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.14(a)(1)-(3), specifically provides in part;

> (a) Any person who commits any of the following acts shall be liable to the District for 3 times the amount of damages which the District sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the District for the costs of a civil action brought to recover penalties or damages, and may be liable to the District for *a* civil penalty of not less than $5,000, and not more than $10,000, for each false claim for which the person:
>
> (1) Knowingly presents, or causes to be presented, to an officer or employee of the District a false claim for payment or approval.

(2) Knowingly makes, uses. or causes to be made or used, a false record or statement to get a false claim paid or approved by the District.

(3) Conspires to defraud the District of Columbia by getting a false claim allowed or paid by the District.

238. By virtue of the above-described acts, among others, Defendant Abbott knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the District of Columbia, for TriCor.

152. Specifically, Defendant has:

- caused hundreds of thousands of fake claims to be presented to the District of Columbia;
- knowingly made, used or caused to be made or used false records to get false claims paid;
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented..

153. The amounts of the false or fraudulent claims to the District of Columbia were material.

154. Plaintiff District of Columbia, being unaware of the falsity of the claims caused to be submitted by the Defendant, and in reliance on the accuracy thereof paid and continues to pay for improperly prescribed TriCor.

COUNT EIGHT
Violations of the Florida False Claims At
Fl. Stat. §§ 68.081-68.09

155. Paragraphs 1 through 154 are incorporated herein as though set forth fully.

156. This Count is brought by Plaintiff-Relator Bergman in the name of the State of Florida under the *qui tam* provisions of Florida False Claims Act, Fl. Stat. §§ 68.081-68.09.

157. Defendant Abbott at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of Florida, including TriCor.

158. Fla. Stat § 68.082(2)(a)-(c) provide liability for any person who:

(a) Knowingly presents, or causes to be presented, to an officer or employee of an agency, a false or fraudulent claim for payment or approval; ... Knowingly makes, uses, or causes to he made or used, a false record or statement to get a false or fraudulent claim paid or approved by an agency;.. , is liable to the state for a civil penalty of not less than $5,500 and not more than $11,000 and for treble the amount of damages the agency sustains because of the act or omission of that person.

(b) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by an agency;... is liable to the state for a civil penalty of not less than $5,500 and not more than $11,000 and for treble the amount of damages the agency sustains because of the act or omission of that person.

(c) Conspires to submit a false claim to an agency or to deceive an agency for the purpose of getting a false or fraudulent claim allowed or paid; ...is liable to the state for a civil penalty of not less than $5,500 and not more than $11,000 and for treble the amount of damages the agency sustains because of the act or omission of that person is liable to the state for a civil penalty of not less than $5,500 and not more than $11,000 and for treble the amount of damages the agency sustains because of the act or omission of that person.

159. By virtue of the above-described acts, among others, Defendant Abbott caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Florida, for TriCor.

160. Specifically, Defendant has:

- caused hundreds of thousands of false claims to be presented to the State of Florida;
- knowingly made, used or caused to be made or used false records to get false claims paid;
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

161. The amounts of the false or fraudulent claims to the State of Florida were material.

162. Plaintiff State of Florida, being unaware of the falsity of the claims caused to he submitted by the defendant, and in reliance on the accuracy thereof paid and continues to pay for improperly prescribed TriCor.

COUNT NINE
Violations of the Georgia State False Medicaid Claims Act,
O.C.G.A. § 49-4-168 *et seq.*

163. Paragraphs 1 through 162 are incorporated herein as though set forth fully.

164. This is a *qui tam* action brought by brought by Bergman and the State of Georgia to recover treble damages, civil penalties and the cost of this action, under the Georgia State False Medicaid Claims Act, O.C.G.A. § 49-4-168 *et. seq.*

165. Defendant Abbott at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of Georgia, including TriCor.

166. Georgia State False Medicaid Claims Act, O.C.G.A. § 49-4-168.1(a), specifically provides in part:

(a) Any person who:

(1) Knowingly presents or causes to he presented to the Georgia Medicaid program a false or fraudulent claim for payment or approval;

(2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Georgia Medicaid program;

(3) Conspires to defraud the Georgia Medicaid program by getting a false or fraudulent claim allowed or paid;

...shall be liable to the State of Georgia for a civil penalty of not less than $5,500.00 and not more than $11,000.00 for each false or fraudulent claim, plus three times the amount of damages which the Georgia Medicaid program sustains because of the act of such person.

167. By virtue of the acts described above, Defendant knowingly presented, or caused to be presented, false or fraudulent claims to the Georgia State Government for payment or approval.

168. Specifically, Defendant has:

- caused hundreds of thousands of false claims to be presented to the State of Georgia;
- knowingly made, used or caused to be made or used false records to get false claims paid;
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

169. For example, TriCor prescriptions for the purposes of non-medically accepted uses would not have been presented but for the illegal incentives and unlawful promotional activities made by Defendant. As a result of this illegal scheme, these claims were improper in whole pursuant to the Georgia State False Medicaid Claims Act.

170. By virtue of the acts described above, Abbott knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the government to approve and pay such false and fraudulent claims.

171. Each prescription that was written as a result of Defendant's illegal marketing practices represents a false or fraudulent record or statement. Each claim for reimbursement for such prescriptions for non-medically accepted uses submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

172. Plaintiff cannot at this time identify all of the false claims for payment that were caused by Abbott's conduct. The false claims were presented by many separate entities, and over many years.

173. The Georgia State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Abbott, paid and continues to pay the claims that would not he paid but for Abbott's false and illegal off-label marketing practices.

174. By reason of Abbott's acts, the Georgia State Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

175. Georgia is entitled to the maximum penalty for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to he made, used, or presented by Abbott.

176. Defendant did not, within a reasonable period of time after first obtaining information as to such violations, furnish such information to officials of the State responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation of the violations, and have not otherwise furnished information to the State regarding the claims for reimbursement at issue. Relator is a private person with direct and

independent knowledge of the allegations in this Complaint, who has brought this action pursuant to Georgia State False Medicaid Claims Act on behalf of herself and the State of Georgia.

177. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Georgia in the operation of its Medicaid program.

COUNT TEN
Violations of the Hawaii False Claims Act
Haw. Rev. Stat. §661-21 *et seq.*

178. Paragraphs 1 through 177 are incorporated herein as though set forth fully.

179. This Count is brought by Plaintiff-Relator Bergman in the name of the State of Hawaii under the *qui tam* provisions of Hawaii False Claims Act, Haw. Rev. Stat. §661-21 *et seq.*

180. Defendant Abbott at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of Hawaii, including TriCor. The Hawaii False Claims Act, Haw. Rev. Stat § 661-21(0(1)-0) specifically provides that any person who:

(1) Knowingly presents, or causes to be presented, to an officer or employee of the State a false or fraudulent claim for payment or approval;

(2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;

(3) Conspires to defraud the State by getting a false or fraudulent claim allowed or paid;

(4) Shall be liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages that the state sustains due to the act of that person.

181. By virtue of the above-described acts, among others, Defendant Abbott knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Hawaii, for TriCor.

182. Specifically, Defendant has:

- caused hundreds of thousands of false claims to he presented to the State of Hawaii;
- knowingly made, used or caused to be made or used false records to get false claims paid;
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

183. The amounts of the false or fraudulent claims to the State of Hawaii were material.

184. Plaintiff State of Hawaii, being unaware of the falsity of the claims caused to be submitted by Defendant, and in reliance on the accuracy thereof paid and continues to pay for improperly prescribed TriCor.

COUNT ELEVEN
Violations of the Louisiana Medical Assistance Programs Integrity Law
Louisiana Rev. Stat. § 46-437 *et seq*.

185. Paragraphs 1 through 184 are incorporated herein as though set forth fully.

186. This Count is brought by Plaintiff-Relator Bergman in the name of the State of Louisiana under the *qui tam* provisions of the Louisiana Medical Assistance Programs Integrity Law, Louisiana Rev, Stat. § 46-437 *et seq*.

187. Defendant Abbott at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of Louisiana, including TriCor.

188. The Louisiana False Claims And Medical Assistance Programs Integrity Law, La. Rev. Stat. § 46-438.3 provides:

> (A) No person shall knowingly present or cause to be presented a false or fraudulent claim.
>
> (B) No person shall knowingly engage in misrepresentation to obtain, or attempt to obtain, payment from medical assistance program funds.
>
> (C) No person shall knowingly make, use, or cause to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the medical assistance programs.

189. By virtue of the above-described acts, among others, Defendant Abbott knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Louisiana, for TriCor.

190. Specifically, Defendant has:

- caused hundreds of thousands of false claims to be presented to the State of Louisiana;
- knowingly made, used or caused to be made or used false records to get false claims paid;
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

191. The amounts of the false or fraudulent claims to the State of Louisiana were material.